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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,280	11/17/2003	Ronald R. Manna	M24-107	4593
7590 08/11/2004			EXAMINER	
R. Neil Sudol 714 Colorado Avenue Bridgeport, CT 06605-1601			ROANE, AARON F	
			ART UNIT	PAPER NUMBER
			3739	
DATE MAILED: 08/11/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/715,280

Applicant(s)

MANNA ET AL.

Examiner

Aaron Roane

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 29-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/17/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-28, drawn to a medical treatment device, classified in class 601, subclass 2.
- II. Claims 29-33, drawn to method for conducting a medical surgical procedure, classified in class 606, subclass 41.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method may be performed with a device that does not have a sheath.

During a telephone conversation with Neil Sudol (Reg. No. 31,669) on 8/2/2004 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-28. Affirmation of this election must be made by applicant in replying to this Office action. Claims

Art Unit: 3739

29-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,648,839 and as also being

Art Unit: 3739

unpatentable over claims 1-22 of U.S. Patent No. 6,736,814. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patents are narrower and recite limitations such that at least one electrode is capable of moving in a transverse direction to longitudinal axis of the device. The claims of the patents recite the structural features of the claimed invention but not vice versa.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 12-15, 17-20, 26, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Farin et al. (USPN 5,776,092).

Regarding claims 1, Farin et al. disclose a surgical instrument comprising a casing (1), an elongate probe (2) mounted to and extending from the casing, the probe having an axis and a free end serving as an operative tip (3); a transducer assembly (not visible) mounted to said casing and operatively connected to said probe for generating vibrations of at least one ultrasonic frequency in the probe; a sheath (9) surrounding the probe; and

at least one electrode member (6) attached to the sheath, the electrode member being connectable to an RF voltage source, see abstract, beginning on col. 3, line 61 and ending on col. 4, line 37 and figures 1a-d and 2a-c.

Regarding claims 2 and 12, Farin et al. further disclose a sheath (9) that is movably mounted to the casing (1) for reciprocable motion along the axis of the probe, whereby the tip (3) of the probe may be alternately covered and exposed, see starting on col. 3, line 53 and ending on col. 4, line 30 and figures 1a-d.

Regarding claims 3, 13 and 14, Farin et al. further disclose the electrode member (6) that are fixed to the sheath, see Farin et al. starting on col. 3, line 53 and ending on col. 4, line 30 and figures 1-4. Furthermore, it should be noted that the electrode member is movable parallel to the axis of said probe (2).

Regarding claims 4 and 15, Farin et al. further disclose the electrode member (6) that is substantially embedded in the sheath and has an exposed tip (6a) proximate to the operative tip (3) of the probe, see Farin et al. starting on col. 3, line 53 and ending on col. 4, line 30 and figures 1-4.

Regarding claim 17, Farin et al. further disclose that "the RF-current applicator is in this embodiment a monopolar ball-shaped coagulation electrode 6a," see col. 4, lines 61-65 and claim 4.

Regarding claims 18-20, Farin et al. disclose a surgical instrument comprising a casing (1), an elongate probe (2) mounted to and extending from the casing, the probe having an axis and a free end serving as an operative tip (3); a transducer assembly (not visible) mounted to said casing and operatively connected to said probe for generating vibrations of at least one ultrasonic frequency in the probe; a sheath (9) surrounding the probe; and at least one electrode member (6) attached to the sheath, the electrode member being connectable to an RF voltage source, see abstract, beginning on col. 3, line 61 and ending on col. 4, line 37 and figures 1a-d and 2a-c. Farin et al. further disclose a sheath (9) that is movably mounted to the casing (1) for reciprocable motion along the axis of the probe, whereby the tip (3) of the probe may be alternately covered and exposed, see starting on col. 3, line 53 and ending on col. 4, line 30 and figures 1a-d.

Regarding claim 26, Farin et al. further disclose the electrode member (6) that is substantially embedded in the sheath and has an exposed tip (6a) proximate to the operative tip (3) of the probe, see Farin et al. starting on col. 3, line 53 and ending on col. 4, line 30 and figures 1-4.

Regarding claim 28, Farin et al. further disclose that "the RF-current applicator is in this embodiment a monopolar ball-shaped coagulation electrode 6a," see col. 4, lines 61-65 and claim 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Farin et al. (USPN 5,776,092) in view of Eggers (USPN 5,611,798).

Regarding claim 5, Farin et al. disclose the claimed invention except for explicitly reciting that said electrode member is one of exactly two electrode members both fixed to said sheath. Eggers et al. disclose a resistively heated cutting and coagulation surgical instrument and teach the use of bipolar versus monopolar electrode modalities, wherein a second electrode is placed in close proximity to the first electrode in order to overcome "some of the more undesirable characteristics of devices in that excessive necrosis is reduced, and current is not passed extensively through the body," see col. 2, lines 9-17. The simplest example of a bipolar device is one with a first and second electrode, wherein the first and second electrodes are at different electrical potentials. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Farin et al., as taught by Eggers, to use a bipolar RF electrode having exactly two electrodes in order to overcome "some of the more undesirable

Art Unit: 3739

characteristics of devices in that excessive necrosis is reduced, and current is not passed extensively through the body.”

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Farin et al. (USPN 5,776,092) in view of Parins et al. (USPN 5,013,312).

Regarding claim 6, Farin et al. disclose the claimed invention except for disclosing a plurality of electrode pairs. Parins et al. disclose an RF/Ultrasonic instrument and teach using a bipolar scalpel mounted in a blade holder designed to contain an ultrasonic transducer. The bipolar electrode or rather scalpel (34) disclosed by Parins et al. constitute a plurality of electrode pairs (first and second pairs: 44, 46 located at the ends and the third pair: 48 and 50 located between the first and second pairs), see abstract and starting on col. 3, line 53 and ending on col. 4, line 30 and figures 1-4. The motivation for using a bipolar electrode is well known in the art and includes higher current densities at operative site. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Farin et al., as taught by Parins et al., to use a bipolar electrode in order to obtain higher current densities at operative site.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references may prove useful. Crowley (USPN 5,630,837) and Suorsa et al. (USPN 6,508,765 B2) both disclose catheter ablation systems that make use of ultrasonic ablation. Broadwin et al. (USPN 4,931,047) and Cucin (USPN 6,394,973 B1) both disclose dual systems comprising elongate bodies having both ultrasonic (non-imaging) and RF coagulation/cauterization capabilities.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/715,280

Page 10

Art Unit: 3739

A.R.

August 6, 2004


MICHAEL PEFFLEY
PRIMARY EXAMINER